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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,247	03/27/2001	David Bar-Or	ISC.007/PCT-US	4924

25871 7590 05/19/2003

SWANSON & BRATSCHEUN L.L.C.  
1745 SHEA CENTER DRIVE  
SUITE 330  
HIGHLANDS RANCH, CO 80129

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/19/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/806,247

Applicant(s)

BAR-OR ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/3/2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 19-22 and 28-82 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 19-22, 28-79, 81 and 82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13 and 80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13, 19-22 and 28-82 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

1. Applicants' Response to Restriction Requirement, received March 03, 2003 Paper # 13, is acknowledged.

Applicants elect, without traverse, Group II, claims 9-13 and 80, specie serum, and species cobalt.

After reconsideration, the examiner withdraws the election of species requirement.

Claims 1-13, 19-22 and 28-82 are pending. Claims 1-8, 19-22, 28-79, 81 and 82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non elected invention.

2. Claims 9-13 and 80 are under consideration.

***Specification***

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
4. This specification contains sequences in the specification, which does not comply with 37 CFR 1.821 (d) for failing to reference to the sequences by use of sequence identifiers, preceded by "SEQ ID NO".

***Priority***

5. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation of Application No. PCT/US99/22905, filed 10/01/1999 which claims priority to ... (enter the number and filing date of priority applications) should be entered following the title

of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 9-13 and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,227,307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications describe a method of detecting the occurrence or non-occurrence of an ischemic state in a patient by contacting a biological sample with a metal ion and a color forming compound and determining the color intensity to detect the presence of unbound metal ions.

8. Claims 9-13 and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,461,875 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications describe a method of detecting the occurrence or non-occurrence of an ischemic state in a patient by contacting a biological sample with a metal ion and measuring the presence of unbound metal ions.

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Art Unit: 1645

9. Claims 9-13 and 80 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,492,179 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications describe a method of detecting the occurrence or non-occurrence of an ischemic state in a patient by contacting a biological sample with a metal ion and measuring the presence of unbound metal ions.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

11. Claims 9-13 and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague and indefinite in the recitation of "known value" in step (d). It is unclear what is the basis for known value and which known value is used to correlate the amount of bound metal ions to determine the occurrence or non-occurrence of an ischemic event.

Claim 9 is vague and indefinite in the recitation of step (b). It is not clear why and how one needs to have a color forming compound to form a colored solution. And also it is not clear how one determines the same color intensity to detect the presence of unbound metal ions and to provide measure of bound metal ions. It is confusing what are the known values to determine the occurrence or non-occurrence of an ischemic event.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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Art Unit: 1645

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 9, 11-13 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Bar-Or et al. (US 5,290,519).

Claims are drawn to a method of detecting the occurrence or non-occurrence of an ischemic event in a patient comprising the steps of:

- a) contacting a biological sample containing albumin with a metal ion;
- b) contacting said mixture with an aqueous color forming compound;
- c) determining the color intensity to detect the presence of unbound metal ions; and
- d) correlating the amount of bound ion to a known value to determine the occurrence or non-occurrence of an ischemic event.

Bar-Or et al. (US Patent No: 5,290,519) teach a method of detecting the occurrence or non-occurrence of an ischemic event in a patient comprising the steps of:

- a) contacting a biological sample containing albumin with a metal ion;
- b) contacting said mixture with an aqueous color forming compound;
- c) determining the color intensity to detect the presence of unbound metal ions; and
- d) correlating the amount of bound ion to a known value to determine the occurrence or non-occurrence of an ischemic event.

See abstract, columns 1, lines 60-65, column 2, lines 24-45, column 3, lines 55-65, column 4, lines 19-31, column 5, lines 24-41, column 6, lines 60-65, example 1 and claims 1-18.

14. Claims 9, 11-13 and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Bar-Or et al. (US 5,227,307).

Claims are drawn to a method of detecting the occurrence or non-occurrence of an ischemic event in a patient comprising the steps of:

- a) contacting a biological sample containing albumin with a metal ion;
- b) contacting said mixture with an aqueous color forming compound;
- c) determining the color intensity to detect the presence of unbound metal ions; and
- d) correlating the amount of bound ion to a known value to determine the occurrence or non-occurrence of an ischemic event.

Bar-Or et al. (US Patent No: 5,227,307) teach a method of detecting the occurrence or non-occurrence of an ischemic event in a patient comprising the steps of:

- a) contacting a biological sample containing albumin with a metal ion;
- b) contacting said mixture with an aqueous color forming compound;
- c) determining the color intensity to detect the presence of unbound metal ions; and
- d) correlating the amount of bound ion to a known value to determine the occurrence or non-occurrence of an ischemic event.

See abstract, columns 2, lines 20-45, column 3, lines 54-64, example 1 and claims 1 and 2-8.

Bar-Or et al. teach a method for detecting ischemic states in a patient by contacting a sample of serum with a metal ion capable of binding to metal binding sites in the sample to form a mixture and then detecting the presence of unbound metal ion to determine the ischemic event (see example 1 and claims). Furthermore, the prior art teaches that several methods could be used to measure the metal ion binding to the sample such as atomic absorption, atomic emission spectroscopy and determining the color intensity by spectrophotometer (see column 3, lines 44-54). Bar-Or et al. teach a variety of metal ion salts including cobalt (see column 5, lines 23-40).

Bar-Or et al. teach that the quantity of free metal ions in the sample may also be detected by

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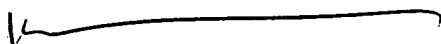
Art Unit: 1645

colorimetric means and teach a variety of color forming compounds (see column 6, lines 20-65).

*Conclusion*

15. No claims are allowed.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached from 7:30 AM - 4 PM on Monday through Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned to is (703) 305-3014.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

May 14, 2002

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER